

## EXHIBIT 153

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**From:** Hernandez, Tracey  
**Sent:** Saturday, February 9, 2013 9:42 PM  
**To:** Connell, Jill  
**Subject:** DEA Compliance Initiatives Presentation  
**Attachments:** DEA Compliance Initiative 2-9-2013.pptx

Jill-  
I added the action items and the estimated completion. If Judy can put them in the Gantt Chart, it would be a big help. Again, the dates are estimates since input is needed from other departments to confirm. I'll add the inspection info tomorrow or early Monday.

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*DEA Compliance  
Improvement Initiative  
2013-2015*

February 2013



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# Executive Summary



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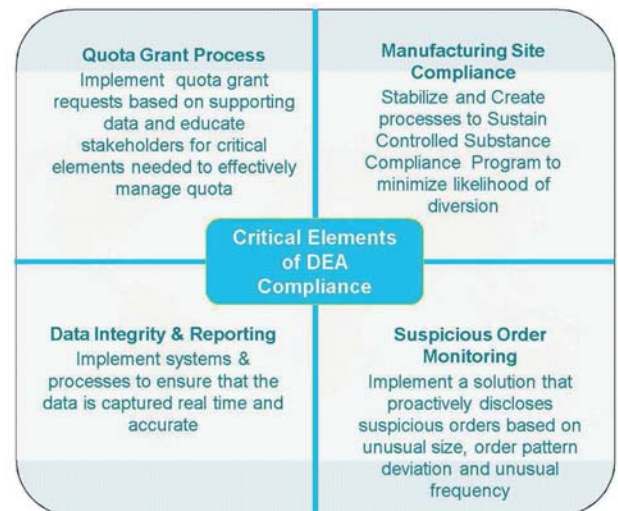
## Executive Summary

### Vision

The Vision for the DEA Compliance Team (DCT) is:

- To drive the company to be proficient at building DEA compliance into product development and commercialization, project initiation, facility modification and computer system design
- To build an environment of accountability, personal responsibility, and individual empowerment as it relates to controlled substance compliance
- As a department, to significantly upgrade, automate and develop procedures for four critical elements of controlled substance management, including:

- ☐ Quota Granting Process
- ☐ Manufacturing Site Compliance
- ☐ Data Integrity & Reporting
- ☐ Suspicious Order Monitoring



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## Executive Summary

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### What the DCT Must Do:

Based on a current state assessment and SWOT analysis, the DEA Compliance Team has defined a set of actions required for them to achieve the vision:

- ☐ Continue to implement in a timely manner previous DEA made commitments
- ☐ Develop mandatory training programs for all employees involved in handling of controlled substances
- ☐ Review and revise DEA related processes and procedures
- ☐ Organize to service internal customers more efficiently, operate more strategically and focus resources on critical elements
- ☐ Execute to the plan

### What EQ&SC Must Do:

In order for Endo to be successful, Qualitest must:

- ☐ Invest time in training, organization, aggregate and agree upon supply chain architecture requirements for all products over the next 3-7 years
- ☐ Invest \$ in improvements to facilities, security and systems
- ☐ Support creating a culture where compliance is embedded into all facets
- ☐ Align business goals to include compliance into its measures
- ☐ Hold ALL employees accountable for driving DEA compliance initiatives as most are team efforts
- ☐ Require supervisors, managers and others to hold their employees accountable and take action when compliance issues are identified



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# Strategic Direction for DCT



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## SWOT Analysis Summary

### Strengths

- ❑ DEA group has significant experience in DEA regulations, quota management and SOMs requirements
- ❑ DEA group has good rapport with DEA HQ personnel and industry peers
- ❑ Knowledge of industry best practices
- ❑ Diverse controlled substance portfolio and licensing & storage capabilities
- ❑ Designated CS personnel embedded within Operations
- ❑ Basic training developed

### Weaknesses

- ❑ DEA related Security and Controls (W1)
- ❑ Lack of Data Visibility, Processes & Systems (W2)
- ❑ Limited Resources - Talent pool and Investments (W3)
- ❑ Lack of Training & Compliance first culture (W4)
- ❑ Inadequate SOMS (W5)
- ❑ Day to day challenges and the depth of compliance activities are not visible to the organization (W6)

### Opportunities

- ❑ Aligning DEA quota grant methodology with sales practices may result in business growth
- ❑ Automation of data and vault/cage expansions will show DEA we are moving in the right direction
- ❑ Strong DEA Compliance can lead to competitive advantages
- ❑ Implementation of LEAN Principals will trim waste
- ❑ Increasing awareness of DEA regulations
- ❑ Increasing alignment with stakeholders

### Threats

- ❑ Increased scrutiny of high profile molecules (T1)
- ❑ Sudden increase in controlled substance volume leads to greater regulatory visibility (T2)
- ❑ Barriers to change (T3)
- ❑ Lack of alignment with respect to Roles & Responsibilities (T4)
- ❑ Further admonitions could result in increasing DEA actions (T5)
- ❑ Number of changes to the business in a short period of time (T6)
- ❑ Local DEA Office is aggressive and is suspicious due to past behavior (T7)



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## *DEA Compliance Team (DCT) Objectives & Value*

***We create value in the eyes of the DCT internal and external stakeholders by enabling a sustainable compliance program***

### **Objectives**

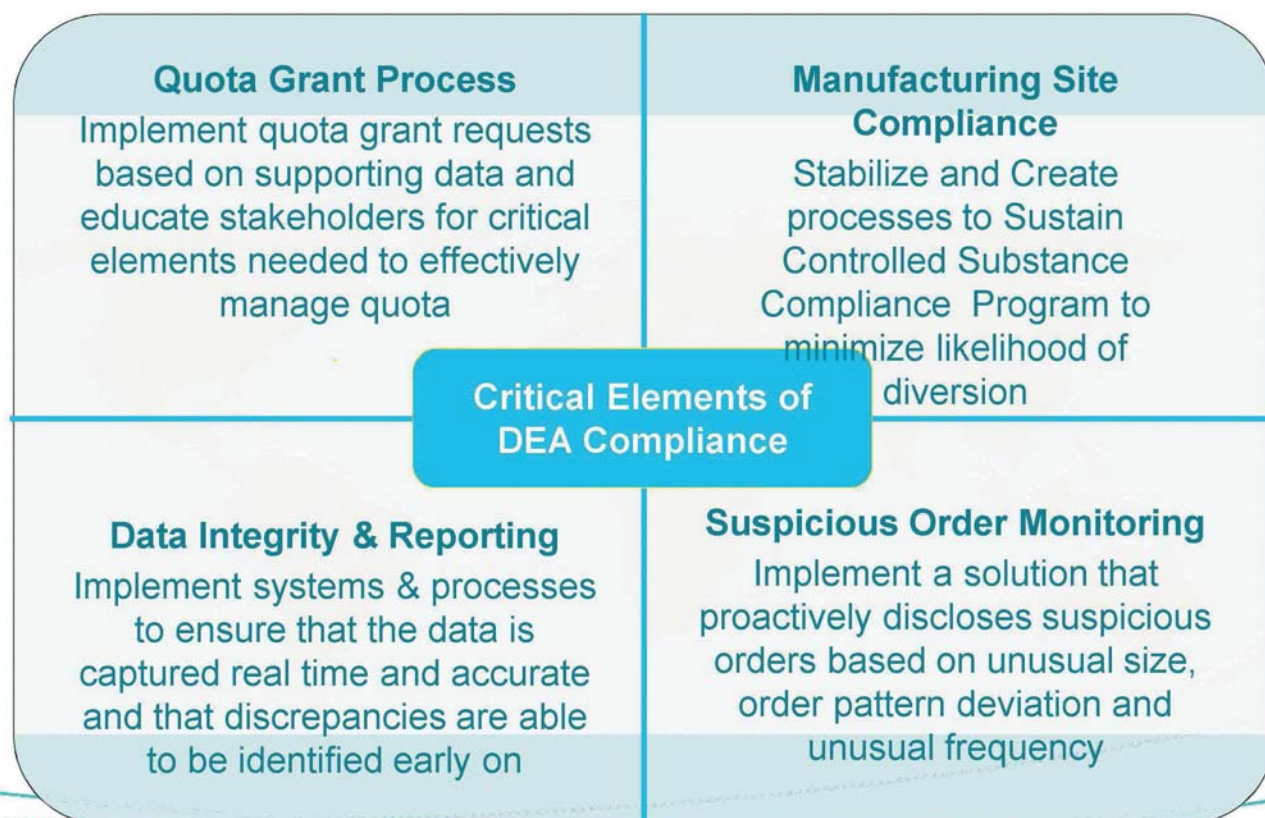
- ☐ Gaining confidence of our stakeholders in Controlled Substance Management program
- ☐ Shared ownership for DEA compliance through education, SOP development and progressive discipline
- ☐ Develop trust in the integrity of our data
- ☐ Simplify and create efficiency in data retrieval
- ☐ Build business relationships between departments and share best practices
- ☐ Ensure compliance with DEA requirements and internal procedures
- ☐ Build confidence in the legitimacy of our customer base (SOMS)
- ☐ Support the Five Year Plan initiatives
- ☐ Improve accountability and prevent theft
- ☐ Enhanced management of quota



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## Core Elements of DCT 2013-2015 Vision

*DCT focus is on four leading practices in managing Compliance*



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*DCT's Action Plan***Recommended Actions**

<b>A1</b>	<b>Close out previous DEA commitments</b>	<ul style="list-style-type: none"> <li>• Build out storage areas as per commitment to bolster security and minimize likelihood of diversion</li> <li>• Add areas requiring further security ex: lab cage, dust collector location etc.</li> <li>• Automate destruction process</li> </ul>
<b>A2</b>	<b>Implement Quota Calculator</b>	<ul style="list-style-type: none"> <li>• Implement quota calculator and educate the organization as to how and when we are eligible for quota, in doing so, minimize DEA quota rejection risks and gain DEA confidence</li> <li>• Process Excellence Team WIP Project to gain visibility to WIP inventory and status</li> </ul>
<b>A3</b>	<b>Real-Time Material Visibility</b>	<ul style="list-style-type: none"> <li>• Create processes and implement systems that reconcile raw material inventory, usage and finished goods data inventory in real-time</li> <li>• Implement solution that reconciles material use in labs</li> <li>• Gain visibility to batch reconciliation percentages, assay results, in-process sampling, etc.</li> </ul>
<b>A4</b>	<b>Data Integrity &amp; Reporting</b>	<ul style="list-style-type: none"> <li>• Develop system solution that minimizes reporting errors to DEA</li> <li>• Create a set of standard reports for use during DEA inspections, internal audits and routine monitoring</li> <li>• Build DEA Compliance requirements and preventative measures into SAP</li> </ul>
<b>A5</b>	<b>Performance Improvement Scorecard/KPIs</b>	<ul style="list-style-type: none"> <li>• Develop DEA Compliance Index tracking performance and embed it into G&amp;Os for the organization</li> </ul>
<b>A6</b>	<b>Training</b>	<ul style="list-style-type: none"> <li>• Ensure all employees handling controlled substances receive DEA Compliance training</li> <li>• Improve procedures to meet job specific requirements ex: Form 222 reports</li> <li>• Create department and company wide Standard Operating Procedures</li> </ul>



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## DCT's Action Plan

### Recommended Actions

A8	<b>Suspicious Order Monitoring System</b>	<ul style="list-style-type: none"> <li>• Implement system solution that identifies orders based on unusual size, orders deviating substantially from normal pattern and order of unusual frequency</li> <li>• Create procedures for escalating exceptions</li> <li>• Revise and implement a new customer addition</li> </ul>
A9	<b>Sustainability Program</b>	<ul style="list-style-type: none"> <li>• Review and Revise Job Descriptions for all impacted functions to include DEA requirements</li> <li>• Develop Internal and External Audit team (Wholesalers &amp; Chains, Pharmacies &amp; CMOs)</li> <li>• Create a culture of Accountability through escalating disciplinary actions for policy violations</li> </ul>
A10	<b>Support the Five Year Plan</b>	<ul style="list-style-type: none"> <li>• Transition R&amp;D activities to Huntsville</li> <li>• Create the Packaging Center of Excellence</li> <li>• Distribution Changes</li> <li>• Product Transfers from Charlotte</li> </ul>



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## Actions to be Linked with DCT Vision & SWOT Analysis

Core Element of DCT Vision	Actions								Support of the Five Year Plan
	Close out previous DEA commitments	Implement Quota Calculator	Real-Time Material Visibility	Data Integrity & Reporting	Performance Improvement Scorecard/ KPIs	Training	Suspicious Order Monitoring System	Sustainability Program	
Quota Grant Process		X	X	X	X	X	X	X	X
Manufacturing Site Compliance	X	X	X	X	X	X	X	X	X
Data Integrity & Reporting	X	X	X	X	X	X		X	X
Suspicious Order Monitoring			X	X	X	X	X	X	
Linkage with the Weaknesses & Threats of the DCT SWOT Analysis	• W1, W4, W5, W6, T1, T2, T4, T5	• W1, W3, W4, W5, T1, T2, T5	W1, W5, T1, T4, T5	• W5, T1, T4, W6	• W1, W4, W5, T5	• W4, T5	• T1	• W5, T4	• W1, W2, W3, T1, T2, T5, T6



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## *Action Area: Close out previous DEA commitments*

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### **Purpose**

Qualitest committed to the following corrective actions in response to a DEA inspection deficiency letter:

- ☐ Accurate accountability of controlled substance waste
- ☐ Filing and proper use of DEA 222 forms
- ☐ Controlled substance storage capacity expansion
- ☐ Improved security measures

### **Proposed Next Steps**

- ☐ Automate the destruction process (sign contract w/vendor, train VCMs, develop report capability) – 1<sup>st</sup> Q 2013
- ☐ Build new vault and cage in Tablet facility, assess vault in Liquids – 1<sup>st</sup> Q 2014
- ☐ Add areas requiring further security (i.e. laboratory control center, dust collector locations, mezzanine, stability chambers, chases, etc.) – 4<sup>th</sup> Q 2014



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## Action Area: Implement Quota Calculator

### Purpose

Provide ability to adequately predict quantity of quota that will be granted by DEA. Have visibility to bottle necks that may be preventing sufficient quota from being granted (i.e. batches on hold, infrequent destructions, rejected batches, utilization of commercial quota by R&D, incorrect package size or strength manufactured, etc.).

### Proposed Next Steps

- Create process for notification of R&D quota needs and rejected batches – 1<sup>st</sup> Q 2013
- Obtain funding and contract with Invistics or design our own quota calculator – 2<sup>nd</sup> Q 2013
  - Imbed IMS data & ARCOS data – 3<sup>rd</sup> Q 2013
  - Correct ARCOS system design issues – 2<sup>nd</sup> Q 2014
  - Train key personnel on the tool to drive routine usage – 3<sup>rd</sup> Q 2013
- Obtain headcount for an individual dedicated to quota – 2<sup>nd</sup> Q 2013



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## *Action Area: Real-Time Material Visibility*

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### **Purpose**

Assure controlled product is visible at all stages so that discrepancies can be identified and resolved quickly.

### **Proposed Next Steps**

- Meet with laboratory personnel and review the possibility of using Trackwise or LIMS for sample accountability/reconciliation – 3<sup>rd</sup> Q 2013
- Assure WIP Process Excellence Team includes controlled substance visibility/accountability in their scope/corrective actions – 4<sup>th</sup> Q 2013
- Obtain resource or work with Quality to capture key pieces of data from batch records in SAP or other system (i.e. reconciliation %, assay results, in-processing samples, etc.) – 3<sup>rd</sup> Q 2013



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## *Action Area: Data Integrity and Reporting*

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### **Purpose**

DEA regulations require accurate reporting of: material receipt, usage in manufacturing and packaging, samples, waste accumulation and disposal, quota filings and sales data.

### **Proposed Next Steps**

- ❑ Map out processes where product is used from the point of receipt to shipment – 2<sup>nd</sup> Q 2013
- ❑ Improve process points where material is used, disposal etc. requiring documentation – 3<sup>rd</sup> Q 2013
- ❑ Implement a system solution (SAP or other tools) to accurately reconcile material usage, ensure real-time data is captured, DEA reports are automated – 1<sup>st</sup> Q 2015
- ❑ Obtain headcount to assist with the multitude of automation projects necessary – 2<sup>nd</sup> Q 2013



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## *Action Area: Performance Improvement Scorecard/KPIs*

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### **Purpose**

Develop tool to measure performance to plan for DEA Compliance team and all departments involved in remediation plan.

### **Proposed Next Steps**

- Embed DEA compliance into the goals and objectives of the organization – 2nd Q 2014
- Assure performance review is tied to these goals and objectives and individuals are held accountable – 4<sup>th</sup> Q 2014



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## Action Area: Training

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### Purpose

Gain employee understanding and engagement in maintaining DEA compliance.

### Proposed Next Steps

- Obtain headcount for Technical Trainer/Writer – 2<sup>nd</sup> Q 2013
- Implement new hire training process – 4<sup>th</sup> Q 2013
- Develop and deliver a robust general training program to all employees – 4<sup>th</sup> Q 2013
- Create SOPs for all controlled substance processes (departmental and company wide) – 2<sup>nd</sup> Q 2015
- Train all effected employees on SOPs as they are created/modified – 2<sup>nd</sup> Q 2015
- Link SOPs training to specific job roles – 1<sup>st</sup> Q 2015



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## Action Area: Suspicious Order Monitoring System

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### Purpose

Implement a robust suspicious order monitoring system that guarantees reliability in the legitimacy of our customer base.

### Proposed Next Steps

- Phase I: Expand to all customers and all controlled products; base threshold on order size, volume and frequency – contract through Cegedim – 1<sup>st</sup> Q 2013
  - Gain approval and hire (one) headcount to investigate, document and report on suspicious orders – 1<sup>st</sup> Q 2013
- Phase II: Integrate SOMS into SAP. Evaluate orders by product mix, API quantity, design trending and reporting capabilities – 4<sup>th</sup> Q 2013
- Phase III: Utilize chargeback and IMS data to “know your customer’s customer”. Implement on-site customer audits, utilizing external audit team – 1<sup>st</sup> Q 2014



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## Action Area: Sustainability Program

### Purpose

Assure that corrective actions put in place remain in place and EVERY employee is held accountable for their role in our DEA compliance. Identify and correct deficiencies before they become issues during DEA inspections.

### Proposed Next Steps

- Work with Training group to determine job categories currently being used for cGMP training. Assign DEA training requirements to each applicable job – 1<sup>st</sup> Q 2015
- Meet with HR to assure that DEA compliance is mentioned as a requirement in these job descriptions and determine the best method for including a measure of compliance in each employee's performance review – 1<sup>st</sup> Q 2015
- Gain headcount approval and hire an audit team (2-4) that would perform internal and external audits (internal departments, suppliers and customers) – 2<sup>nd</sup> Q 2013
- Assure that progressive discipline program being worked on by HR is applied to DEA activities – 2<sup>nd</sup> Q 2013
- Work towards a mindset of less tolerance for individuals suspected of diversion activities. Don't wait for person to be caught; minimize risk to the business – 3<sup>rd</sup> Q 2013



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## *Action Area: Support of the Five Year Plan*

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### **Purpose**

Assure that implementation of each change occurs seamlessly and does not put our DEA compliance at risk. Changes include R&D transition, distribution changes, product transfers from Charlotte, packaging center of excellence.

### **Proposed Next Steps**

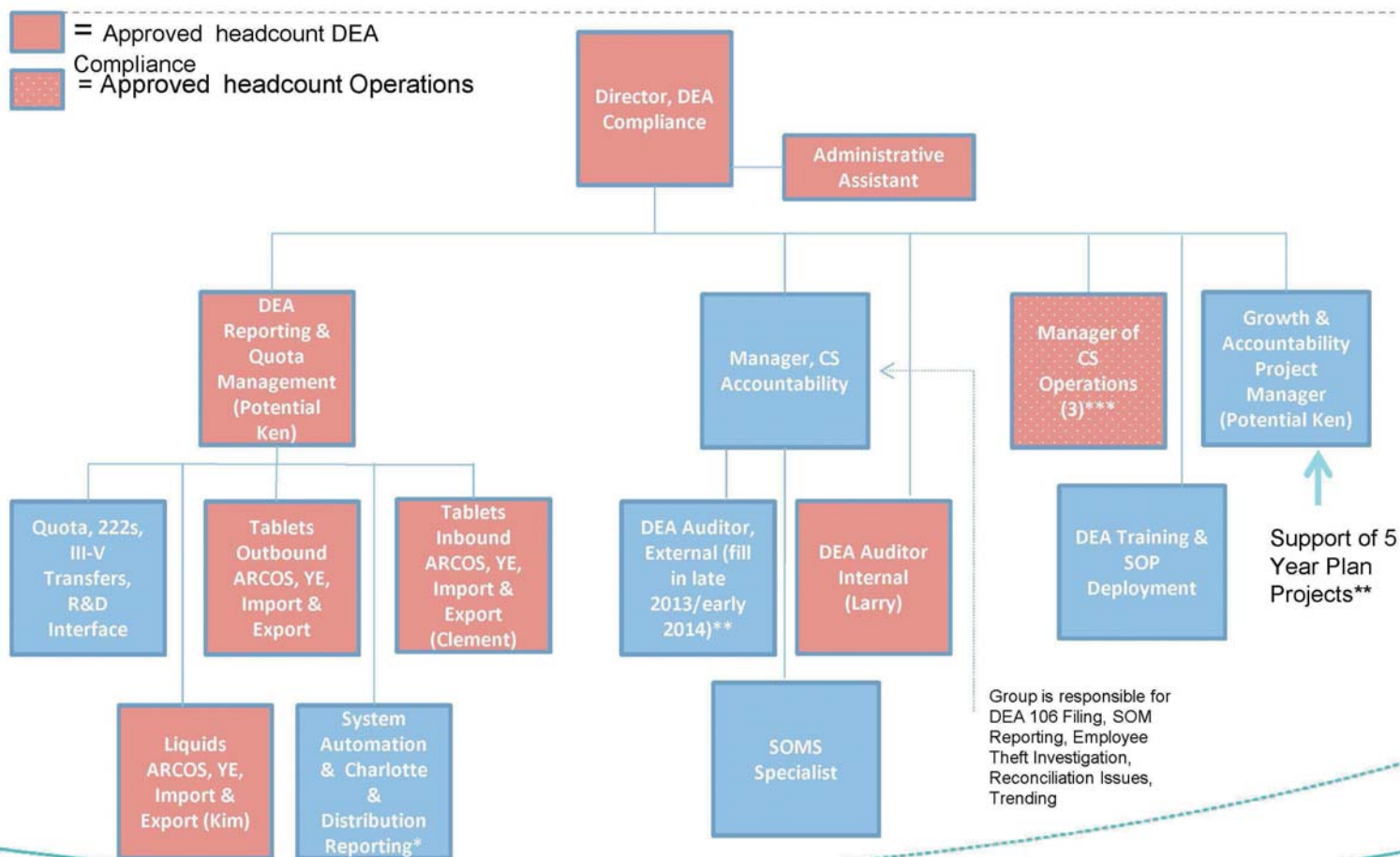
- Integrate DEA Compliance into project teams to assure necessary DEA approvals, license changes, storage capacity, transfer documents, etc. occur. – 2<sup>nd</sup> Q 2013
- Obtain approval for necessary resource - DEA project manager role – 2<sup>nd</sup> Q 2013



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## DCT – Organization Structure



- -- Assumes Reporting for Charlotte & Distribution will be decreasing over the next one to two years.
- \*\* - Audits suppliers, customers, etc.
- \*\*\* - Works w/Trainer to update/create Mfg SOPs.



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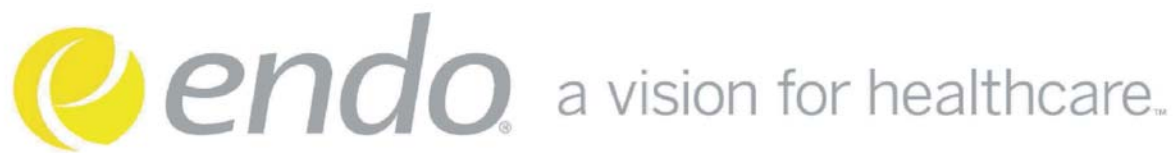
## Next Steps

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- ❑ Resources - Headcount Approval & Funding
- ❑ Execute action plan, monitor, share progress and issues with EQ&SC Team
- ❑ Comprehensive action plan (FMEA, DEA/Security Plan, Inspection Action Plans); combine all and work with responsible departments to obtain cost and timeline for completion of each task.



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## *DEA Inspections History*

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